

**REMARKS**

The double patenting rejection of the Office Action is objected to. MPEP 804 requires that "[a]ny obviousness-type double patenting rejection should make clear: (A) [t]he differences between the inventions defined by the conflicting claims...and (B) [t]he reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent." The Office Action fails to follow either of those requirements, instead simply citing the "relatively broad subject matter claimed in the instant application."

Nevertheless, in order to facilitate the prosecution of this application and conserve the resources of the Office and of the assignee, a terminal disclaimer accompanies this paper.

**35 U.S.C. §102**

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

**Claims 1-7**

The rejection of claims 1-7 is respectfully traversed.

Claim 1 claims "[a] method of cutting a plug of tissue from the wall of a blood vessel, the method comprising: piercing the wall of the blood vessel, at a location in the wall through which blood previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough; cutting a plug from the wall of the blood vessel around the opening to create a hole in the blood vessel; and inserting a trocar around the piercing element and into the hole in the wall of the blood vessel."

In contrast, U.S. Pat. No. 5,910,153 to Mayenberger ("Mayenberger") does not expressly or inherently describe each and every element of the claims. First, Mayenberger does not expressly or inherently describe "piercing the wall of the blood vessel, at a location in the wall through which blood previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough." (emphasis added). Instead, Mayenberger describes a "cutting member 28 [that] is first of all introduced into a vessel through a cut in the wall 38 of the vessel." (Mayenberger; col. 7, lines 6-9) (emphasis added). A cut in the wall 38 of a blood vessel necessarily allows blood to escape, directly contrary to the express requirement of claim 1 of piercing the wall at a location "through which blood previously had been substantially prevented from escaping." (emphasis added).

Second, Mayenberger does not expressly or inherently describe the claimed "inserting a trocar...into the hole in the wall of the blood vessel." (emphasis added). The sleeve 18 of Mayenberger is at all times outside the wall of the blood vessel and is never inserted "into the hole in the wall of the blood vessel," such as illustrated at Figures 1-2. The sections of Mayenberger cited in the Office Action (Figure 4 and col. 7, line 46 to col. 8, line 22) also fail to describe "inserting a trocar...into the hole in the wall of the blood vessel," as does the remainder of Mayenberger.

Thus, Mayenberger does not expressly or inherently describe each and every element of claim 1, and Applicants believe claim 1 is in condition for allowance. Claims 2-7 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 8-15

The rejection of claims 8-15 is respectfully traversed.

Claim 8 claims “[a] method for making an opening in a vessel, comprising: piercing the wall of the vessel with a piercing element; retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.” (emphasis added).

In contrast, Mayenberger does not disclose “retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.” (emphasis added) The cutting member 28 of Mayenberger only moves linearly along the tubular shaft 1 – that is, along the axis of the tubular shaft 1. (e.g., col. 7, lines 13-16; Figures 1-2, 5-6). Indeed, the inner diameter of the tubular shaft 1 and the outer diameter of the piercing element 28 are substantially the same, such that the piercing element 28 cannot be moved away from the longitudinal centerline of the tubular shaft 1. (e.g., Figure 6). Thus, Mayenberger does not disclose the claimed “retracting said piercing element at least partially into a tube having a lumen; and moving said piercing element away from the longitudinal centerline of said tube.”

As a result, Mayenberger does not expressly or inherently describe each and every element of claim 8, and Applicants believe claim 8 is in condition for allowance. Claims 9-15 depend from claim 8, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 16-23

The rejection of claims 16-23 is respectfully traversed.

Claim 16 claims “[a] method for making an opening in the wall of a hollow tissue structure, comprising: piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping, with a piercing element to create an opening therethrough; retracting the piercing element toward an

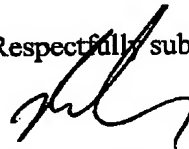
opening in a body to cut a tissue plug from the wall of the hollow tissue structure; and capturing the tissue plug with said piercing element.." (emphasis added).

The discussion above with regard to claim 1 is equally applicable here. Mayenberger fails to describe the claimed "piercing the wall of the hollow tissue structure, at a location in the wall through which fluid previously had been substantially prevented from escaping." As a result, Mayenberger does not expressly or inherently describe each and every element of claim 16, and Applicants believe claim 16 is in condition for allowance. Claims 17-23 depend from claim 16, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar  
Attorney for Cardica, Inc.  
Reg. No. 45,076  
Tel. No. (650) 331-7162